AMENDMENTS/REMARKS

Claims 1-19 and 21-25 are pending and stand rejected. Claim 20 was previously canceled. Applicants respectfully request reconsideration and allowance based on the following remarks.

Amendments

Applicants amend independent claims 1, 15, and 19 to each include the recitations of claims 23-25, as well as to clarify that the "loop of suture" is a "length of suture." Support for the amendments related to the recitations of claims 23-25 was previously provided in the Office Action response dated June 28, 2007. Support for the amendment related to the "strand of suture" is found throughout the specification and figures, but at least at page 3, lines 4-13, page 5, lines 26-27, page 6, lines 3-6, 9-11, and 19-26, and page 11, lines 1-3, 7-13, and 22-24. Claims 6, 7, and 21-25 are canceled. No new matter is added.

Prior Art Rejections

Applicants have amended the features of claims 23-25 into each independent claim. As claims 23-25 were not rejected under 35 U.S.C. § 102(b), the amendments obviate the anticipation rejections made in the outstanding office action. The only remaining issue is whether Donnelly and Pedlick render the claims obvious.

Rejection of Claims 23-25

In particular, with respect to these claims, the Examiner states:

> 21. **Claims 21-25 are rejected under 35 U.S.C. 103(a) as unpatentable over Donnelly et al. (US 6,773,436) in view of Pedlick.**

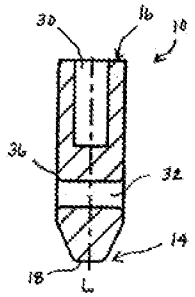
22. The device of Donnelly discloses (see paragraph 7 above) the invention substantially as claimed except for suture channel is substantially perpendicular with the longitudinal axis of the body. However, Pedlick discloses and suture anchor comprising, among other things, a suture channel that perpendicular with the longitudinal axis of the body. Therefore, it would have been obvious to one of ordinary skill in the art to modify the suture channel of Donnelly device with the suture channel as disclosed by Pedlick for the purpose of simplify the manufacturing of the anchor because the oblique angled channel with the longitudinal axis of the body is more difficult to create than a channel that perpendicular with the longitudinal axis of the body. Further, applicant has not disclosed that the suture channel substantially transverse with the longitudinal axis of the body provides an advantage, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected the suture channel of Donnelly device, Pedlick device, and applicant's invention, to perform equally well.

Applicants first review the two references, Donnelly and Pedlick, before showing how their combination does not render the claims obvious.

Donnelly US 6,773,436

Independent claims 1 and 15 recite a suture anchor and a system for anchoring tissue to a bone, respectively, that are configured to toggle and anchor inside a bone cavity based on tension being applied to a suture in a suture channel formed in an elongate body of the suture anchor. Likewise, independent claim 19 recites a method of attaching tissue to bone in a patient's body that includes toggling this suture anchor based on tension being applied to a suture in a suture channel formed in an elongate body of the suture anchor such that a flared portion of the anchor penetrates into an inner surface of the bone cavity. More particularly, the suture anchors in each of the independent claims are configured so that the suture channel (32) formed in the elongate body is oriented substantially transverse at right angles to a longitudinal axis of symmetry of the body, as illustrated in Figure 2B, reproduced below. The suture channel (32) further has a

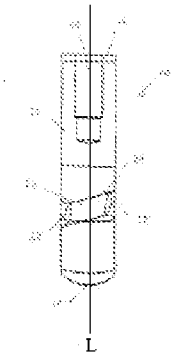
centerline that is laterally offset with respect to the longitudinal axis of symmetry of the body in a direction opposite to the direction of a flared portion of the suture anchor. In use, the device is toggled by applying tension to a suture within the channel to effect engagement with the bone.



SECTION A—A

FIG. 2B

Donnelly does not disclose, teach, or suggest a suture anchor with the recited configuration. The suture channel of Donnelly requires that the suture channel be ***obliquely angled*** with respect to the longitudinal axis of the body of the anchor. In particular, as shown in Figure 1B of Donnelly which is also reproduced herein to the left with reference label L added, the suture channel 24 is *obliquely angled* with respect to the longitudinal axis L of the body. This is completely opposite to the recitations of claims 1, 15, and 19, which require that the suture channel be oriented "*substantially transverse at right angles* to the longitudinal axis of symmetry of the body" of the anchor.



This difference between the teachings of Donnelly and the opposite recitation in the present claims has a purpose: Donnelly seeks to provide a bone anchor that can toggle in two planes. As a solution, Donnelly provides an anchor with an obliquely-angled suture channel. In contrast, the claimed invention is concerned with configuring a suture anchor so as to be suitable for reattaching soft tissue to bone in a small joint such as in the hand or skull. Claim 1, 15, and 19 thus provides a suture anchor having a suture channel oriented transversely to the longitudinal axis of the anchor.

In addition, Donnelly, at least in its one suture channel embodiments, generally provides this obliquely angled suture channel in a configuration that puts its center line on the longitudinal axis rather than being laterally offset from its longitudinal axis. This configuration is illustrated, for example, in Figure 1A of Donnelly.

Accordingly, Donnelly fails to disclose, teach, or suggest a suture anchor as recited having the required suture channel configuration to achieve the desired (and recited) toggling in independent claims 1, 15, and 19.

Pedlick US 6,270,518

Pedlick does not disclose, teach, or suggest a suture anchor with the claimed configuration – as recognized by the Examiner by the lack of an anticipation rejection of claims 23-25 over Pedlick. The claims recite a suture anchor having "an elongate body" and "a flared portion." The suture channel has "a centerline that is laterally offset with respect to the longitudinal axis of symmetry of the body in a direction opposite to the flared portion."

As shown in Figures 3 and 16, which are reproduced below with the longitudinal axis of symmetry of the body L added (as well as, for Fig. 16, a line that defines the elongate body from the flared portion so that the axis of symmetry for the body can be determined), the suture channel of Pedlick is aligned with the longitudinal axis of symmetry of the suture anchor body – it is not offset from it in a direction that is opposite to the direction of the flared portion. Pedlick fails to disclose, teach, or suggest at least this claim element of a centerline of the suture channel being laterally offset with respect to the longitudinal axis of symmetry of the elongate body.

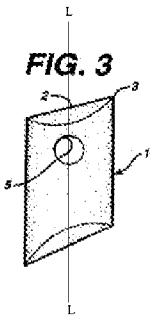


FIG. 3

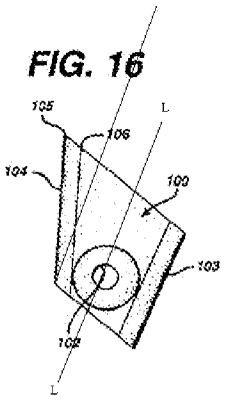


FIG. 16

The fact that the recited suture channel configuration is missing from the disclosure and teachings of Pedlick relates to a lack of teaching by Pedlick of other elements of the independent claims. Independent claims 1 and 15 further recite a suture anchor that is configured to ***toggle*** and anchor inside a bone cavity ***based on tension being applied to a suture in the suture channel***. In a like manner, independent method claim 19 recites a method of attaching tissue to a bone in a patient's body that includes toggling the suture anchor by pulling on the attached suture strand such that the flared portion of the anchor penetrates into an inner surface of the bone cavity. This capability/action is provided based upon the offset nature of the suture channel with respect to the longitudinal axis of symmetry of the elongate suture anchor body. As one would expect, Pedlick teaches a completely different system/method for rotating its anchor inside bone than is recited in Applicants claims.

Pedlick does not disclose, teach, or suggest a suture anchor or method that relies upon the application of tension to the suture, as recited in Applicants' claims. Rather, Pedlick teaches a wedge-shaped suture anchor that is adapted to receive an installation tool for insertion into a bone hole. In use, the user applies a downward pressure to the installation tool to position the anchor within the bone hole. Once positioned, the user *releases* this downward pressure in preparation for withdrawing the device, causing the shaft of the tool to straighten. This straightening force causes one of the edges of the anchor to press into the wall of the bone cavity. As a result, the anchor pivots or rotates within the bone hole such that the anchor securely

engages the wall of the one hole. This method is further described in detail at Column 19, lines 33-41 of Pedlick:

> Next, the user withdraws installation tool 400 from bore hole 600. As downward pressure on installation tool 400 is released (to be replaced by opposite upward pressure during tool withdrawal), the flexed shaft tip 404 tries to straighten itself, causing the suture anchors sharp, well-defined biting edge 322 to press into wall 602, and causing the suture anchor to pivot slightly in the bore hole so that the suture anchor's cam surface 326 securely engages wall 606 of the bore hole. As the user retracts installation tool 400 from bore hole 600, rearward movement of installation tool 400 causes progressively more distal portions of the suture anchor's cam surface 326 to come into engagement with wall 606 of the bore hole.

See also, column 9, lines 17-38 (for the embodiment illustrated in FIGS. 9 and 10); column 9, lines 39-62 (for the embodiment illustrated in FIGS. 11 and 12); column 11, lines 40-56 (for the embodiment illustrated in FIGS. 19-25); and column 12, lines 61-65 (for the embodiment illustrated in FIG. 26). ***In every one of the many embodiments in Pedlick, it is the installation tool that rotates the anchor***.

Thus, Pedlick teaches a device and method that are the exact opposite of the device and method recited by Applicants' claims. While Applicants' claims require the application of tension to a suture to effect anchoring of the device within bone, Pedlick's device requires the "flexed shaft tip" of an installation tool to pivot the device as it straightens. Pedlick relies on the installation tool to pivot the device, while Applicants' device toggles based on pulling on the suture thread.

Accordingly, Pedlick also fails to disclose, teach, or suggest the toggling based upon tension placed on the suture in the suture channel as recited in each of independent claims 1, 15, and 19.

The Present Invention

Applicants' goal in developing the novel suture anchors disclosed and claimed in the present application is to reattach tissue to small bones in the body. In the Background, the Inventors discuss the problems with inserting known anchors in the small bones of the hand and skull. (*See*, paragraph [0007].) In paragraph [0011] of the application, the Inventors note that "[t]he suture anchor of the present invention is sized and configured for insertion in a small bone such as would be found in the hand or skull." In particular, and as stated at paragraph [0028] of the published application (and also in the Declaration of Jose Lizardi Pursuant to Rule 132 at ¶¶ 4 and 6):

> The suture anchors 10, 110 of the present invention are configured and sized such that they can be used, with sutures, in the repair or reconstruction of collateral ligaments, flexor and extensor tendon at the proximal interphalangeal (PIP), distal interphalangeal (DIP), and metacarpal interphalangeal (MIP) joints of all digits in a patient's hand. Additionally, these anchors 10, 110 can be used to attach soft tissue to the parietal, temporal ridge, frontal, mandible, maxilla, zygoma, and periorbital bones of the skull. Therefore, the suture anchors 10, 110 should have a length sufficient to enable them to properly seat within a small bone such as those mentioned, but be sized and configured to be effective in a surgery to reattach soft tissue to such bone.

As a result, the suture anchors of Applicants' device have an elongate body with a length preferably in the range of about 2 to about 6 mm as recited in dependent claims 2 and 17.

Prior to Applicants' invention, the use of suture anchors in these small bones were limited primarily to suture anchors that used screw threads or barbs to hold the anchors in place. (*See*, Declaration of Jose Lizardi Pursuant to Rule 132, ¶ 7 and the references cited therein.) While toggling anchors were known at the time of the invention, they were used in larger bones, such as the bones of the shoulder disclosed for procedures described in the Pedlick patent. (*Id.*) A goal of the present inventors was to develop a smaller toggling anchor that could bring the advantages in ease of use and grip in bone of toggling anchors to procedures in smaller bones

that lacked the space for such toggling anchors in the past. The inventors achieved this goal in part simply by making a toggling anchor that was smaller than those on the market, but they also achieved this goal by designing a specific toggling action by configuring the suture channel as claimed. By using the claimed configuration, the anchor could be toggled simply by putting tension on the suture thread – using the anchor inserter to toggle the anchor was not required (and indeed, there would not be room for it) – and having the anchor toggle in a predetermined direction and way by placing the suture channel in its recited transverse and offset configuration. Because the toggling can be directed, a surgeon can plan for the directed toggling and can choose an orientation for the bone hole in which there is sufficient room for the anchor to toggle, even within small bone spaces. (*See*, *Id.* at ¶¶ 4, 6-7.)

Following the present invention, in 2003 the assignee of the present application released two products based upon the claimed design, the MiniLok and MicroFix suture anchors. These products have received a favorable commercial reception and are still marketed and sold today. (*See*, *Id.* at ¶ 8.)

The Claims are Not Obvious Over the Asserted Combination of Donnelly and Pedlick

As discussed above, each of amended independent claims 1, 15, and 19 are at least separately distinguishable over Donnelly and Pedlick. However, the Examiner believes that the combination of the two references renders the claims obvious. More particularly, the Examiner argues that it would have been obvious to one of ordinary skill in the art to replace the obliquely angled suture channel of the Donnelly anchor with the suture channel as disclosed by Pedlick for the purpose of simplifying the manufacturing of the anchor, and further argues that Applicants have failed to show that having the suture channel substantially transverse with respect to the longitudinal axis of the body provides an advantage or solves a stated problem. Applicants disagree.

MPEP § 2141(II)(B) notes that "[t]he references must be considered as a whole and ***must suggest the desirability and thus the obviousness of making the combination***." (Emphasis added.) Because a new invention generally relies on building blocks discovered long before the new invention, it is important to identify a reason that would have prompted such a combination

in determining if the invention is obvious in light of these building blocks and the knowledge of those of ordinary skill in the art. *KSR Int'l Co. v. Teleflex Inc.*, 127 S.Ct. 1727, 1741 (Apr. 30, 2007). "Identification in the prior art of each individual part claimed is insufficient to defeat patentability of the whole claimed invention." *In re Kotzab*, 217 F.3d 1365, 1370, 55 USPQ2d 1313, 1317 (Fed. Cir. 2000) (citation omitted).

In contrast to these strong and recent warnings, the Examiner's proposed reason for combining Pedlick with Donnelly has no basis in the record or in fact. The Examiner states that it would "simplify the manufacturing of the anchor" to combine the transverse suture channel of Pedlick with Donnelly. Neither reference, nor any other cited reference, makes this suggestion. In addition, the opposite would appear to be true. First, there is no reason to believe that forming the suture channel in any one direction would be simpler than forming the suture channel in any other direction. Further, Applicants' directed toggling requires that the suture channel be "substantially transverse" and "at right angles" – Donnelly merely requires an oblique angle, with no particular angle preferred. It would seem that Applicants' configuration would require more precise machining of a very small part – as opposed to Donnelly's obique angle in a larger anchor – and as a result the Examiner's proposed rationale would actually make it harder to manufacture an anchor of the invention rather than simpler.

In addition, the proposed combination would frustrate the purpose of the Donnelly reference. According to MPEP § 2143.01(V), "[i]f [the] proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the propose modification" (citation omitted). Further, in accordance with MPEP § 2143.01(VI), "[i]f the proposed modification or combination of the prior art would change the principle of operation of the prior art invention being modified, then the teachings of the references are not sufficient to render the claims *prima facie* obvious" (citation omitted). (Emphasis not added.) Modifying the suture anchor 10 of Donnelly to replace the obliquely angled suture channel 24 with the suture channel 5, 102, or 330 as disclosed by Pedlick would violate both of these rules.

Donnelly requires the obliquely angled suture channel 24 to operate as it is designed. In fact, the specification specifically states as much at Col. 4, lines 17-20, describing that it is "***[b]ecause of the uniquely angled suture channel 24*** of bone anchor 10, a suture strand extending through this channel 24 can effect a toggling action in the bone anchor 10 in two planes when tension is applied." (Emphasis added.) If the Examiner's proposed modification was made, i.e. replacing the obliquely angled suture channel 24 with the suture channel 5, 102, or 300 of Pedlick, the suture anchor 10 of Donnelly would no longer toggle in two planes as it was specifically designed and intended to do. In light of the teachings of Donnelly, and specifically in light of the importance placed on the obliquely angled suture channel 24 by Donnelly, no person having ordinary skill in the art would have been motivated to replace the obliquely angled suture channel 24 with a suture channel like those taught by Pedlick. Such a modification would defeat the purpose of the Donnelly design, and further, would likely cause the suture anchor 10 of Donnelly to not operate as it was intended to operate.

In addition, even if one were to follow the Examiner's instruction that "it would have been obvious to one of ordinary skill in the art to modify the suture channel of the Donnelly device with the suture channel as disclosed by Pedlick," this combination would not result in the configuration claimed. The suture channel embodiments of Donnelly (as opposed to the slotted and two hole embodiments that have an even more complicated toggling action that would raise a whole host of new non-obviousness arguments) generally have a suture channel whose centerline runs through the axis of symmetry of the elongate body of the suture anchor – just at an oblique angle. The transverse suture channels illustrated in Pedlick likewise run through the longitudinal axis of symmetry. ***Even if one were to make the combination suggested by the Examiner, the suture channel would not be laterally offset from the longitudinal axis of symmetry as required by the claims***. Still further, Donnelly expressly teaches away from the Examiner's proposed combination by touting the virtues of Donnelly's complex toggling action.

Finally, the Examiner further asserts in her rejection of claims 21-25 that Applicants have not shown that having the suture channel "oriented substantially transverse at right angles to the longitudinal axis of symmetry of the body" provides an advantage or solves a stated problem. However, as detailed in the attached Declaration of Jose E. Lizardi Pursuant to Rule 132 (and in

the portions of the application quoted above), the claimed anchors, systems, and method do indeed provide a significant advantage in comparison to anchors, systems, and methods that existed prior to Applicants' invention. In particular, the geometry and resulting performance in light of the geometry make the claimed devices and method much better suited for use in small areas, such as in bones in the vicinity of the face and hands, as well as other small bones in the body. (*Id.* at ¶ 6; application at paragraphs [0007, 0011, and 0028], for example.) Prior to Applicants' invention, most of the suture anchors used in such small areas in the body relied on screws, threads, and barbs to attach tissue to bone. (*Id.* at ¶ 7.) However, since Applicants' assignee introduced the claimed suture anchor for sale in 2003, it has found a great deal of success. (*Id.* at ¶ 8.) In fact, the device is still marketed and sold today, particularly for use in surgeries where tissue needs to be attached to small bone. (*Id.*) The success of the claimed devices is directly attributable to the unique design employed by Applicants, and thus provides further evidence of the advantage that the suture anchor provides and the Examiner requested to see in the most recent Office Action.

Accordingly, independent claims 1, 15, and 19, as well as any claims which depend therefrom, are allowable over Donnelly and Pedlick.

Nonstatutory Double Patenting Rejection

The Examiner rejects claim 19 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. 7,232,455 to Pedlick et al. In particular, the Examiner asserts that "[a]lthough the conflicting claims are not identical, they are not patentably distinct from each other." The Examiner then provides no further support as to exactly how the method of Applicants' claim 19 is patentably indistinct from the method of claim 1 of the cited Pedlick reference.

Pending method claim 19 is patentably distinct from claim 1 of the cited Pedlick reference at least because the two claims recite different methods for toggling the suture anchor in the bore. More specifically, claim 1 of Pedlick claims the step of "pulling the inserter to cause the cam portion to move along said second wall portion and the anchor to rotate in the bore…," which is patentably distinct from the method recited in claim 19, "toggling the suture anchor by

pulling on the attached suture strand…" At least because the two methods claim a different way of toggling or rotating the suture anchor, pending method claim 19 is patentably distinct from claim 1 of the cited Pedlick reference and is thus allowable.

Conclusion

Applicants submit that the pending claims are in condition for allowance, and allowance thereof is requested. If the Examiner believes that further communication would expedite the prosecution of this application, Applicants encourage the Examiner to contact the undersigned attorney.

Dated: January 22, 2008

Respectfully submitted,

Ronald E. Cahill
Registration No.: 38,403
NUTTER MCCLENNEN & FISH LLP
World Trade Center West
155 Seaport Boulevard
Boston, Massachusetts 02210-2604
(617) 439-2000
(617) 310-9000 (Fax)
Attorney for Applicants

1702005.1